Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of wet-cupping in treatment of BALB/c-mice infected by Leishmania major. Pilot Randomized Clinical Trial

Protocol summary

Summary

Cutaneous leishmaniasis (CL) caused by Leishmania major is common in Middle East countries. Most therapies are limited and there is no effective vaccine for leishmaniasis. It has been reported that wet-cupping (a Complimentary and Alternative Medicine technique) has been effective in treatment of drug resistant CL. This study aim is to determine the efficacy of wet-cupping in treatment of L. major infected BALB/C mice. We have designed a randomized clinical trial with 6 mice in each experimental and control group.This study will perform at medical laboratory in Kermanshah University of Medical Science. 12 male BALB/c mice, aged 8-10 weeks, will be used (six mice for each experimental and control group). Each mouse will be infected with L. major on left hind footpad. Mice in intervention group will undergo wet-cupping once a week, up to 6 weeks. Footpad thickness index will be measured for continues 7 weeks in both groups. Moreover, spleen and lymph node cell culture will be done at week 9 after inoculation. Levels of IFN- γ and IL-4 will be measured as the markers of TH1 and TH2, respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306021310N9**
Registration date: **2013-06-03, 1392/03/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-06-03, 1392/03/13

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Science

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of wet-cupping in treatment of BALB/c-mice infected by Leishmania major. Pilot Randomized Clinical Trial

Public title

Effectiveness of wet-cupping on cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

male BALB/c mice, aged 8-10 weeks

Age

From **8 years** old to **10 years** old

Gender

Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **12**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kermanshah University of Medical Sciences
Street address
Shahid Beheshti Blv
City
Kermanshah
Postal code
Approval date
2012-12-21, 1391/10/01
Ethics committee reference number
911045

Health conditions studied

1

Description of health condition studied
Cutaneous leishmaniasis
ICD-10 code
B55.1
ICD-10 code description
Cutaneous leishmaniasis

Primary outcomes

1

Description
Footpad thickness index
Timepoint
Weekly for continues 7 weeks
Method of measurement
Vernier caliper

2

Description
Spleen and lymph node cell culture
Timepoint
Week 9
Method of measurement
Spleen and lymph node cell culture

3

Description
Levels of IFN- γ and IL-4
Timepoint
Week 9
Method of measurement
IFN- γ and IL-4 levels in supernatant

Secondary outcomes

empty

Intervention groups

1

Description
Wet-cupping
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical laboratory in Kermanshah University of Medical Science
Full name of responsible person
Street address
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Nourizad
Street address
Kermanshah University of Medical Sciences
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty